REMARKS

Amendments to the Specification

The specification has been amended to correct various grammatical and typographical errors. No new matter has been added.

Claim Amendments

For ease of reference due to the length of the claims as filed and the numerous amendments made, claims 1-20 have been cancelled and new claims 21-35 are presented herein. No new matter has been added.

Rejection of Claims 6, 13, 14 and 20 Under 35 U.S.C. §101

Claims 6, 13, 14 and 20 are rejected under 35 U.S.C. §101 as being substantial duplicates of claims 5, 7, 8 and 15, respectively. Claims 1-20 have been cancelled, but Applicant addresses this rejection as it may be applied to claims 25 and 32-35.

Claim 25 depends from claim 21 and further characterizes the effect of desirable modification, i.e., that it produces a substantial increase in oral bioavailability and plasma half life as compared to non-modified Δ5-androstene compounds. Similarly claim 34 depends from claims 27-30 and further characterizes the effect of the desirable modification. Thus claims 25 and 34 provide functional limitations on the desired modifications.

Claims 32, 33 and 35 depend from any of claims 27-31 and further describe the desired response produced upon administration of the compound.

Applicant believes that, as amended, the claims are not duplicative of one another and respectfully requests reconsideration and withdrawal of the rejection.

Rejection of Claims 12, 16 and 18 Under 35 U.S.C. §112, First Paragraph

Claims 12, 16 and 18 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. More specifically, the Examiner states that undue experimentation would be required to practice the invention as claimed because Applicant has allegedly not shown the effect of the recited compounds in the improvement of

any condition. Applicant notes that claims 12, 16 and 18 have been cancelled but addresses the rejection in the event that it is maintained against the newly presented claims.

Applicant respectfully disagrees with the Examiner's position. It is well known in the art that DHEA and 7-keto-DHEA are beneficial with regard to the recited conditions/functions. For example, the specification references a number of published studies and reports which have demonstrated the efficacy of DHEA and 7-keto-DHEA (see, for example, paragraphs [0028]-[0065]). An improvement of these prior art compounds provided by the present invention is an increase in oral bioavailability and plasma half-life as a result of the disclosed modifications to the Δ5-androstene compound. Without wishing to be bound by theory, it is believed that these modifications render the DHEA molecule more lipophilic, permitting circulation through the lymphatic system and avoiding rapid metabolism by the liver. It is not expected that the disclosed modifications will impact the functional effect of the compound, and the Examiner has provided no evidence to support the position that the disclosed modifications would significantly change the *in vivo* effect of administration of Δ5-androstene compounds. Accordingly it is respectfully requested that the Examiner reconsider and withdraw the rejection.

Rejection of Claims 1-20 Under 35 U.S.C. §112, Second Paragraph

Claims 1-20 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner alleges that the recitation of "a desired response" is unclear; newly presented claims 27-35 recite a method for improving health in a human.

The Examiner notes that several compounds are recited in which O is listed as having an alpha or beta position despite the impossibility of rotation for the O substituent. The claims presented herein obviate this issue.

The Examiner alleges that the claims are unclear due to the recitation of the term "includes," stating that it is unclear what else is intended by the phrase "desired response." As noted above, claims 27-35 recite "improving health," and claims 32, 33 and 35 recite specific improvements in health. The use of the term "comprising" in this context clearly indicates that the modified compound has one or more of the recited specific effects, and that additional

beneficial improvements in the health of the human are within the scope of the claim when combined with the recited specific effects.

The Examiner alleges that the claims are unclear in the recitation of "improved." Applicant respectfully disagrees, as it is clear in the context of the method that the improvement is judged by comparing the parameter (e.g., memory, immune response, etc.) after administration of the supplement with the parameter in the absence of the supplement.

Finally, the Examiner alleges that claim 18 is unclear in the recitation of an improvement in symptoms of one or more ailments. Again, Applicant respectfully disagrees and addresses the rejection as it may be applied by the Examiner to claim 35. Claim 35 recites a method wherein the supplement is administered to a human having symptoms of one or more of HIV/Aids, heart disease, lupus, diabetes, depression, low sex drive, and muscular wasting disease and wherein the improvement in health comprises an improvement in said one or more of said symptoms. The skilled artisan is readily able to determine the symptoms associated with each of the recited ailments and to identify improvement in one or more of these symptoms after administration of the recited supplement.

Accordingly, Applicant respectfully submits that for these reasons the claims as presented even more particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 5-8, 12-17, 19 and 20 Under 35 U.S.C. §102(b)

Claims 1, 5-8, 12-17, 19 and 20 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Lardy *et al.* (WO 95/06472; Reference N).

As an initial matter, Applicant respectfully requests clarification from the Examiner as to the status of Claims 2-4, 9-11 and 18 with regard to this rejection. Specifically, Applicant would appreciate confirmation from the Examiner that these claims were deemed free of the cited art, notwithstanding their cancellation herein.

Lardy *et al.* disclose a discrete group of compounds (compounds (1)-(10); page 4, lines 8-18) "and derivatives thereof wherein one or more of the hydroxyl or keto substituents is a group convertible thereto by hydrolysis." (page 4, lines19-21). Applicant understands the language relating to derivatives to mean that derivatives are purportedly disclosed which, while not identical to one of compounds (1)-(10) due to a variation in one or more hydroxyl or keto

substituents, can be converted to one of compounds (1)-(10) by hydrolysis of the differing hydroxyl or keto substituent(s). Lardy *et al.* go on to identify specific hydrolysable groups at page 4, lines 22-30; specifically Lardy *et al.* identify hydroxyl groups esterified with an acid selected from one of four groups as suitable hydrolysable groups. In addition Lardy *et al.* disclose that compounds (1)-(10) may be administered as a carbamate or "other such derivative capable of releasing the specified steroid within the intestinal tract, blood and/or body tissue." (page 4, line 31 through page 5, line 2)

Applicant notes that claims 21-35 presented herein recite specific modifications selected from the group consisting of a tetrahydropyranol ether, a 1-methoxycyclopentane ether, a cyclopent-1'-enyl ether and combinations thereof at the third carbon, the seventeenth carbon or both the third and seventeenth carbons (e.g., claim 21, claim 26). None of these modifications are disclosed by Lardy *et al.*

First, the specific compounds (1)-(10) of Lardy *et al.* do not read on Applicant's claims, as amended, and thus do not anticipate the claimed invention.

Next, Lardy *et al.* purport to broadly disclose derivatives of compounds (1)-(10) wherein one or more of the hydroxyl or keto substituents is a group convertible thereto by hydrolysis. However this broad disclosure does not anticipate the specifically recited modifications of the claims submitted herewith. More particularly, this disclosure does not allow one of ordinary skill in the art to "at once envisage" the specifically recited modifications as required (MPEP §2131.02), particularly in view of the further disclosure by Lardy *et al.* that the derivations of a moiety may serve a variety of beneficial functions including stabilization of the steroid, flavoring or obscuring the natural flavor of the steroid or affecting the rate of absorption of the steroid (page 5, lines 4-8). Indeed, based on the limited ability of ethers to be hydrolyzed, particularly *in vivo*, as discussed below, it is not at all clear which, if any, of the specific modifications recited in the claims would even be encompassed by the generic disclosure of Lardy *et al.* relating to derivatives of compounds (1)-(10).

Lardy *et al.* disclose by name only ester-based modifications or carbamates (esters of carbamic acid), while the claims, as amended, recite ether-based modifications. As the Examiner is no doubt aware, ethers have the general structure R–O–R' (an oxygen atom connected to two (substituted) alkyl or aryl groups), while esters have the general structure R-C(=O)-O-R. There are significant differences between the functional properties of ethers and esters as well. For

example, while esters may be readily hydrolyzed, ethers are typically hydrolyzed only under drastic conditions such as heating with boron tribromide or boiling in hydrobromic acid. Lower mineral acids containing a halogen, such as hydrochloric acid, will cleave ethers, but only very slowly.

Moreover, the modifications recited in the current claims do not encompass the four specific groups of acids Lardy *et al.* disclose as being esterified to the alcohol in their disclosed derivatives. Thus it is clear that the specifically disclosed ester-based modifications are not the same as the instantly claimed ether-based modification, and one of ordinary skill in the art would not "at once envisage" the recited ether-based modifications in the disclosure of Lardy *et al.* Accordingly the disclosure of Lardy *et al.* does not anticipate the invention as currently claimed. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above remarks and amendments, Applicant respectfully submits that the application is in condition for allowance. If the Examiner believes that a telephone call would be useful in expediting the allowance of the application, the Examiner is invited to contact the undersigned.

Applicant believes that no fee is due for the response other than the fees provided for on the accompanying transmittal. However, if an additional fee is due, please charge Deposit Account No. 50-3655, from which the undersigned is authorized to draw, under order number BKNL-001-101.

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Respectfully submitted,

By Lisa M. Treannie

Lisa M. Treannie, Esq.
Registration No.: 41,368
Morse, Barnes-Brown & Pendleton, P.C.
Reservoir Place
1601 Trapelo Road, Suite 205
Waltham, MA 02451
781-622-5930
Attorneys for Applicant